DM-10/2003 ATTORNEY DOCKET NO: KCX-742 (19795)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| /                | <b>3</b>               | 3                   | <b>/</b>  |            |                          |                                 |
|------------------|------------------------|---------------------|---|------------|--------------------------|---------------------------------|
| In re            | A Pricat               | Spend !             | Ning Wei  | )          | Group Art Unit:          | 1645                            |
| Serial           | No:                    |                     | 10/718,996  | )<br>)     | Examiner:                | Unknown                         |
| Filed:           |                        |                     | November 21, 2003   | )          | Our Account No:          | 04-1403                         |
| Confi            | rmation                | No:                 | 9086  | . )        | Customer No:             | 22827                           |
| Title:           | Method                 | l Of Redu           | acing The Sensitivity Of Assay Devices  | ; )        |                          |                                 |
| U.S. F<br>Post C | Patent an<br>Office Bo |                     | nark Office   |            |                          | •                               |
| Sir:             |                        |                     |   |            |                          |                                 |
|                  | ollowing<br>1.97, and  |                     | formation Disclosure Statement for the  | captioned  | patent application, pur  | suant to 37 CFR Sections        |
| 1.[x]            | Attacl                 | ned hereto          | o is:   |            |                          | **                              |
|                  | a.[x]                  | A list o            | of materials for consideration per Rule 9   | 98(a)(1):  | 2 page(s)                |                                 |
|                  | b.[x]                  |                     | ole copy of each patent, publication, or of or as indicated on the attached list(s): m(s)                                       | other item | listed per Rule 98(1)(2  | ), unless not required per Ru   |
|                  | c.[]                   | thereof             | ch <u>non-English language item listed, pu</u><br>as it is presently understood by the ind<br>of such items:                    |            |                          |                                 |
|                  |                        |                     | n explanation is provided in the Search with any enclosed translation into Engli  |            | om a corresponding app   | lication enclosed herewith      |
| 2.[x]            | This I                 | nformatio           | on Disclosure Statement is being filed [4]  | СНЕСК (    | ONE]:                    |                                 |
|                  | a.[x]                  | after a             | N THREE MONTHS of the application request for continued examination, <u>OR</u> which ever event occurs last, <u>WHERE</u> ired. | BEFORE     | the mailing date of a fi | rst Office Action on the        |
|                  | b.[ ]                  |                     | R the time periods of section 2.a above, that otherwise closes prosecution, WHE   |            |                          |                                 |
|                  |                        | i.[ ]               | Certification per Rule 97(e); OR  |            |                          |                                 |
|                  |                        | ii[]                | Filing Fee per Rule 17(p)   |            |                          | \$180.00                        |
|                  | c.[]                   |                     | R a Final Action <u>OR</u> Notice of Allowand (d) submitted herewith is:  | ce, but BI | EFORE payment of the     | issue fee, <u>WHEREFORE</u> per |
|                  |                        | i.                  | Certification per Rule 97(e); AND   |            |                          |                                 |
|                  |                        | ii.                 | Filing fee per Rule 17(p)   | ••••••     |                          | \$180.00                        |
| 3.[]             |                        | 7(e) Cert<br>CK ONE | ification; per Rule 97(e), the undersign<br>:   | ed certify | ing party make the follo | wing certification statement    |
|                  | a.[ ]                  |                     | ch item of information contained in this nication from a foreign patent office in   |            |                          |                                 |

b.[] That no item of information contained in this Information Disclosure Statement was cited in a foreign patent office in a counterpart foreign application and to the knowledge of the undersigned after making a reasonable inquiry, was known to any individual designated in Rule 56(c) more than three months prior to the filing of this statement.

prior to the filing of this statement; OR

|       |                                  | CERTIFYING PARTY (if different from bottomade by signer per signature below).  | om signature; omission here indicates that certification is being   |
|-------|----------------------------------|--|---|
|       |                                  | Name:  | Signature:  |
|       |                                  | Address:   | Date:   |
| 4.[x] | author<br>herewinow or<br>overpa | ized hereafter, or any fees in addition to the fee(s<br>ith or concerning any paper filed hereafter, and w<br>r hereafter relative to this application and the res | missioner is hereby authorized to charge any fee specifically s) filed, or asserted to be filed, or which should have been filed which may be required under Rules 16-18 (deficiency only) alting official document under Rule 20, or credit any a hereof for which purpose a duplicate copy of this sheet is the issue fee in this case. |
| 5.[x] |                                  | IFICATE OF MAILING: This Information Disc<br>PLETE ONE]:   | closure Statement is being filed pursuant to [CHECK AND   |
|       | a.[x]                            | First Class Mail Certificate of Mailing under R  | ule 8:  |
|       |                                  | I hereby certify that this correspondence and at<br>the United States Postal Service as first class m  | ny referenced attachment and/or fee are being deposited with hail in an envelope addressed to the:  |
|       |                                  | Commissioner for Patents U.S. Patent and Trademark Office Post Office Box 1450   | *   |
|       |                                  | Alexandria, VA 22313-1450  |   |
|       |                                  | on <u>December 14, 2004</u> .  |   |
|       |                                  | Sandra S. Perkins (Typed/printed name of person mailing paper of   | or fee)   |
|       |                                  | Dando Sterker  | <u> </u>  |
|       |                                  | (Signature of person mailing paper or fee)   |   |
|       | b.[ ]                            | "Express Mail" Certificate under Rule 10:  |   |
|       |                                  | "Express Mail" - Label No<br>Date of Deposit   |   |
|       |                                  | I hereby certify that this paper and all attachme<br>Service "Express Mail Post Office to Addresses<br>is addressed to the:  | nts and any fee are being deposited with the U.S. Postal e" service under 37 CFR 1.10 on the date indicated above and   |
|       |                                  | Commissioner for Patents U.S. Patent and Trademark Office Post Office Box 1450   |   |
|       |                                  | Alexandria, VA 22313-1450.   |   |
|       |                                  | (Typed/printed name of person mailing paper o  | r fee)  |
|       |                                  | (Signature of person mailing paper or fee)   |   |
|       | fice Box                         |  | DORITY & MANNING, ATTORNEYS AT LAW, P.A.  |
|       |                                  | 29602 USA<br>o.: 22827   | By: Christina L. Mangelsen, Patent Agent  |
|       |                                  | 4-271-1592<br>4-233-7342   | Reg. No: 50,244   |
|       |                                  | · · · · · · · · · · · · · · · · · ·  | Signature: Mastra Minuscin  |
|       |                                  |  | Date: December 14, 2004   |

| (Rev. 5/92) Information Tacks Statement List | Attorney Docket Number:<br>KCX-742 (19795) | Serial Number:<br>10/718,996 |
|--|--|------------------------------|
| By Applicant(s)                              | Applicant                                  | :                            |
| Under 37 CFR Section 1.98(a) (1)             | Ning Wei                                   |                              |
| (Use several sheets if necessary)            | Filing Date:                               | Group Art Unit:              |
|  | November 21, 2003                          | 1645                         |
|  | Confirmation No:                           |                              |
|  | 9086                                       |                              |

NOTE:

If no indication is made in the column marked "COPY NOTE," the required legible copy of the corresponding item is submitted herewith; otherwise, a copy is not required and/or not submitted, for the following reason(s) [corresponding reason number is listed in "COPY NOTE" column]"

- (1) This item is cumulative, per Rule 98©
- (2) A copy of this item was previously cited by or submitted to the U.S. Patent and Trademark Office in:

| USSN_           | , filed                               | , 01 |
|-----------------|---------------------------------------|------|
| USSN_           | , filed;                              |      |
| Relied on under | 35 U.S.C. Section 120, per Rule 98(d) |      |

- (3) Both reasons (1) and (2) apply
- (4) No legible complete copy is possessed, in custody of controlled, or readily available
- (5) Per the U.S. Patent and Trademark Office's waiver of Rule 98(a)(2)(i), the item is a U.S. patent or patent application publication, and the present application was filed after June 30, 2003.

| EXAMINER<br>INITIALS | PATENTEE NAME    | PA | TEN | ΓNU | ISSUE<br>DATE | COPY<br>NOTE |     |   |            |   |
|----------------------|------------------|----|-----|-----|---------------|--------------|-----|---|------------|---|
|                      | Lihme, et al.    | 5  | 7   | 7   | 0             | 4            | T 1 | 6 | 06/23/1998 | 5 |
|                      | Henkens, et al.  | 6  | 3   | 9   | 1             | 5            | 5   | 8 | 05/21/2002 | 5 |
|                      | Zhang            | 6  | 6   | 7   | 0             | 1            | 1   | 5 | 12/30/2003 | 5 |
|                      | Wong, et al.     | 6  | 7   | 8   | 7             | 3            | 6   | 8 | 09/07/2004 | 5 |
|                      | Jacobson, et al. |    | 8   | 11  | 5             | 2            | 1   | 8 | 11/09/2004 | 5 |

| U.S. PATENT APPLICATION PUBLICATIONS |                  |      |   |      |      |      |     |                     |              |            |   |
|--------------------------------------|------------------|------|---|------|------|------|-----|---------------------|--------------|------------|---|
| EXAMINER<br>INITIALS                 | APPLICANT'S NAME |      |   | BLIC | CATI | ON I | NUM | PUBLICATION<br>DATE | COPY<br>NOTE |            |   |
|                                      | Huang, et al.    | 2003 | 0 | 1    | 7    | 8    | 3   | 0                   | 9            | 09/25/2003 | 5 |
|                                      |                  |      |   |      |      |      |     | l                   | Ī            |            |   |

| FOREIGN PATENT DOCUMENTS  |  |                 |  |  |  |  |  |  |                     |     |             |     |  |
|---------------------------|--|-----------------|--|--|--|--|--|--|---------------------|-----|-------------|-----|--|
| EXAMINER COUNTRY INITIALS |  | DOCUMENT NUMBER |  |  |  |  |  |  | PUBLICATION<br>DATE | TRA | TRANSLATION |     |  |
|                           |  |                 |  |  |  |  |  |  |                     | YES | NO          | N/A |  |
|                           |  |                 |  |  |  |  |  |  |                     |     |             |     |  |

<sup>\*&</sup>quot;NO" means that no copy of an English language translation is within the possession, custody, or control of, or is readily available to any individual designated in Rule 56(c).

(Rev. 5/92) Attorney Docket Number: Serial Number: Information Disclosure State

By Apple 38 (8) KCX-742 (19795) 10/718,996 Applicant: Under 37 CFR Section 1.98(a) (1) Ning Wei (Use several sheets if necessary) Filing Date: Group Art Unit: 1645 November 21, 2003 Confirmation No: 9086

| EXAMINER | OTHER DOCUMEN   | NTS                            | COPY   |
|----------|---|--------------------------------|--------|
| INITIALS | Specify author (if any), Title, Pertinent Pages,        | Date & Place of Publication    | NOTE   |
|          | Article - New Use of Cyanosilane Coupling               |                                |        |
|          | Agent for Direct Binding of Antibodies to               |                                |        |
|          | Silica Supports. Physicochemical                        |                                |        |
|          | Characterization of Molecularly                         | j                              |        |
|          | Bioengineered Layers, Sandrine Falipou,                 |                                |        |
|          | Jean-Marc Chovelon, Claude Martelet,                    |                                | **     |
|          | Jacqueline Margonari and Dominique                      |                                |        |
|          | Cathignol, Bioconjugate Chem., Vol. 10, No.             |                                |        |
|          | 3, 1999, pp. 346-353                                    |                                |        |
|          | PCT Search Report and Written Opinion for               | 09/28/2004                     |        |
|          | PCT/US2004/006412                                       |                                |        |
|          | PCT Search Report and Written Opinion for               | 09/28/2004                     |        |
|          | PCT/US2004/006414                                       |                                |        |
| EXAMINER |   | DATE CONSIDERED                |        |
|          |   |                                |        |
|          | initial if citation considered, whether or not citation |                                |        |
| (        | draw line through citation if not in conformance a      | nd not considered. Include a c | opy of |
| 1        | his form with the next communication to applican        | nt.                            |        |